

**REMARKS/ARGUMENTS**

Claims 25-35, 37-48 and 50-56 are pending. By this Amendment, claims 25, 27, 50 and 52 are amended, claim 49 is canceled, and claims 53-56 are added. Reconsideration in view of the above amendments and the following remarks are respectfully requested.

At the outset, it is noted that the rejection has been made final in error. Specifically, the finality is improper and premature because the December 12, 2007 Office Action rejected the combination of claims 25 and 36 based on Budding (U.S. Patent No. 5,464,412) in view of Kaji (U.S. Patent No. 6,142,931), whereas claim 25, which was amended to include the subject matter of canceled claim 36, now stands rejected based on Kaji alone, i.e., the amendment to claim 25 (to include dependent claim 36) did not necessitate the new grounds of rejection. Therefore, Applicant respectfully requests that the amendments provided herewith be entered as a matter of right since the finality of the rejection was made prematurely.

In addition, while the Examiner still primarily relies on Kaji to reject a majority of the claims, including both independent claims, the Examiner has provided no response to Applicant's arguments set forth in the June 12, 2008 Amendment. Those arguments were incorporated by reference, some of which are repeated below.

Turning now to the Office Action, claims 50 and 52 were rejected under 35 U.S.C. §112, second paragraph. This rejection is respectfully traversed.

In regard to claim 50, the Examiner takes the position that the phrase "the window is positioned beyond the distal end of the first hollowed body" is unclear and vague. Applicant respectfully submits that the claim language is clear on its face and therefore satisfies the requirements of 35 U.S.C. §112, second paragraph. The arrangement is also clearly shown in, for example, Figure 1, where the operating window 8 is shown positioned beyond a distal end of

the first hollow body 4. Applicant respectfully notes that Figure 2 shows the distal end 4c of the first hollowed body, and thus it is clear that Figure 1 shows that the operating window 8 is positioned beyond the distal end of the first hollowed body 4.

In regard to claim 52, amendments are provided herewith which define the basic steps employed in the "Sias" method for treating hemorrhoids.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 25 now includes the subject matter of canceled claim 49 and specifies that the operating window is of constant size. As shown and described in Kaji, the operating window 33 is not of constant size, as claimed. In the Office Action, it is specified that the opening window 32, 33 is of constant size. However, while openings 31, 32 in respective cylindrical bodies are of constant size, the *treatment window* 33 is not of constant size, as claimed. New dependent claim 56 further emphasizes this feature by specifying that the operating window is of constant size independent of the rotational positions of the first and second hollow bodies relative to one another. Clearly, the operating window 33 in Kaji is dependent on the relative angular positions of the first and second sheets 3 and 4.

In regard to independent claim 27, Kaji does not teach or disclose that the reciprocal angular positions correspond to the same number of positions that can be taken up by the window. Figures 5A and 5B of Kaji clearly show that the treatment windows 31 and 32 comprising sheaths 3 and 4, respectively, are intended for suitably receiving a surgical tool. The windows can be rotated relative to one another since they may be overlapped, not overlapped, or only partially overlapped. Moreover, Kaji does not teach or suggest an angular positioning element that is provided to adjust the relative angular position of the second hollow body in the

first hollow body in preset reciprocal angular positions. Kaji provides no teaching or disclosure to adjust the relative angular positions of sheets 3 and 4 in preset angular positions.

In addition, Kaji does not teach or suggest that the first and second hollow bodies can be rotated relative to one another while the operating window maintains a constant size and allows access to the rectal mucous membrane at all of said reciprocal angular positions. Again, Kaji's sheaths 3 and 4 are rotated relative to one another so as to vary the size of the treatment window 33.

In addition, Kaji does not teach or suggest the subject matter of dependent claims. For example, claim 50 specifies that the operating window (in the second hollow body) is positioned beyond the distal end of the first hollow body. In the Office Action, the Examiner states that the window is positioned beyond the distal end of the first hollow body 3 (towards the proximal direction). As explained above in relation to the rejection under 35 U.S.C. §112, second paragraph, Kaji simply does not teach or suggest the claimed subject matter since treatment window 33 is formed as part of both sheaths 3 and 4, and therefore the treatment window cannot extend beyond the distal end of the first hollow body.

New dependent claim 54 similarly distinguishes over Kaji, since Kaji does not teach that the window of the second hollow body is provided at a distal end of the second hollow body, and the second hollowed body protrudes outside and beyond a distal end of the first hollow body.

In addition, Kaji does not teach that the preset angular positions correspond to the arterial branches of the patient's rectal wall (claim 51). In particular, Kaji does not teach that the sheaths 3 and 4 are rotatable at preset angular positions, and in any event Kaji does not teach that the preset angular positions correspond to the arterial branches of the patient's rectal wall, as

specified in claim 51. The Office Action does not address claim 51 directly, although it is mentioned in the heading in paragraph 7 of the Office Action.

Furthermore, Kaji does not teach or suggest a method for treat hemorrhoids based on the “Sias” method as set forth in claim 52. In the Office Action, the Examiner takes the position that Kaji discloses a method for treating hemorrhoids based on the “Sias” method, but provides no explanation as to where Kaji discloses such a method. In any event, Applicant respectfully submits that Kaji does not disclose treatment of hemorrhoids using the “Sias” method. Kaji is an endoscope tube unit which is used to endoscopically perform mucosa resecting procedures that can be carried out without the drawbacks of prior art apparatuses. The “Sias” method involves the use of an anoscope to perform through-the-anus surgical operations, such as the treatment of hemorrhoids using the “Sias” method. Kaji’s apparatus relates to complicated surgical procedures, involving cutting off, sewing of the mucosa, while the “Sias” method simply involves ligatures of hemorrhoidal arteries, which can be carried out without anesthesia in a day hospital. Moreover, the differences existing between through-the-anus surgical operations (e.g., the “Sias” method) and endoscopically performable mucosa resection procedures (Kaji) are also differentiated in Kaji (see column 1, lines 12-18).

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 37 was rejected under 35 U.S.C. §103(a) over Kaji. Claim 37 specifies that the operating window is defined by a U-shaped cut. In the Office Action, it is conceded that Kaji does not disclose such a U-shaped cut. However, the Office Action takes the position that it would have been obvious to have made window 32 to have a U-shaped or C-shaped cut to facilitate insertion of larger surgical instruments, since it has been held that the change or shape of the prior art device is a design consideration within the skill of the art.

Applicant respectfully submits that the selection of the U-shaped operating window is not a matter of design choice, but was specifically selected for specific reasons. In particular, operating window 8 is delimited by a U-shaped cut, the convex part of which reaches near the female thread F of the second hollowed body 6. Operating window is made in such a way that the convex end of the U-shaped cut corresponds to the point that can be reached by the end of the index finger of the hand of a person of average build by inserting the index finger inside the anoscope. In this way, the operating window 8 constitutes the area where the operator can enter in direct contact with the rectal mucous membrane to carry out the “Z” surgical sutures provided by the “Sias” method. See page 8, lines 28-33.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 29-33 and 39-43 were rejected under 35 U.S.C. §103(a) over Kaji in view of Chikama (U.S. Patent No. 5,345,926). However, Chikama does not make up for the deficiencies noted above in respect to Kaji, and was only relied upon to allegedly show the claimed truncated cone-shape portions.

In regard to claim 42, the Examiner takes the position that the claim notches which are arranged at 1 o'clock, 3 o'clock, 5 o'clock, 7 o'clock, 9 o'clock and 11 o'clock would be an obvious rearrangement of parts. However, Applicant respectfully submits that the arrangement of the notches at these positions corresponds to the positions of the six arterial branches of the patient's rectum. Therefore, the positions of the notches were specifically selected for specific reason, and do not constitute an obvious rearrangement of parts.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 44-48 were rejected under 35 U.S.C. §103(a) over Kaji in view of Chikama and further in view of Kura (U.S. Patent No. 5,507,717). This rejection is respectfully traversed at

least because Kura does not make up for the deficiencies noted above in relation to Kaji and Chikama, and was only relied upon to show locking teeth.

Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicant respectfully submits that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4462-13.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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